REMARKS/ARGUMENTS

Applicants have not cancelled, added, or amended any claims. Accordingly, claims 1 and 53-57 are pending in the application. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Rejection of the Claims Under 35 U.S.C. §103(a) Should Be Withdrawn

Claim 1 stands rejected under 35 U.S.C. §103(a) as being obvious in light of Chow *et al.* ("the '729 patent") in view of Gerhart *et al.* ("the '112 patent") and further in view of Sander *et al.* ("the '629 patent"). This rejection is respectfully traversed.

Applicants respectfully assert that the Examiner continues to misunderstand the present invention. By way of background, a key feature of the invention as claimed is that the composition comprises a compound wherein a portion of at least one of the chemical elements calcium, oxygen and phosphorous in the compound are substituted by another chemical element having an ionic radius of approximately 0.1 to 0.6Å. Other aspects of the invention as claimed are that the compound is bioresorbable and the composition comprises a pharmaceutical agent.

The Examiner is correct in stating that the '729 patent discloses a bone cement composition comprising hydroxyapatite and tetracalcium phosphate possessing improved mechanical strength properties, that is easy to mold into desired contours, and that sets at ambient temperatures. The Examiner cites the '112 patent for the disclosure of a bone cement comprising a calcium phosphate ceramic and resorbable calcium salt dispersed in a cross-linked biodegradable polyester matrix that may contain drugs such as antibiotics. The Examiner is also correct in stating that the '629 patent discloses a composition for bone repair which comprises biocompatible particles of a polymer dispersed in a matrix where biocompatible particles of any size may be used in the composition and the matrix material can be conveniently comminuted to the appropriate particle size for mixing.

However, in spite of the disclosures described by the Examiner in the '729, '112, and '628 patents, the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art reference(s) must teach or suggest all the claim limitations. MPEP §2143, citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine the reference teachings to arrive at the claimed invention. The Examiner appears to focus on particle size as a critical feature of the present invention. For example, the Examiner concedes that while the '729 patent "does not disclose ionic radius (i.e. size of particles or size of constituent elements within the matrix)," the Examiner points to the '629 patent for the disclosure that "biocompatible particles of any size may be used in the composition and that matrix material can be conveniently comminuted to the appropriate particle size." The Examiner goes on to state that "By substituting elements having ionic radii that is convenient, thereby control[ling] the particle size in the composition forming the bone cement matrix, one of ordinary skill would expect to obtain a composition that can be molded and implanted into a bone defective site." However, in the present invention, the selection of chemical elements that can substitute for the chemical elements calcium, oxygen, or phosphorous in a calcium phosphate lattice has nothing to do with a desire to control particle size, but is instead motivated by the desire to stabilize the composition (see, e.g., page 3, lines 23 to 26 of the specification). One of skill in the art seeking ways to stabilize a novel biomaterial compound would not turn to references teaching the control of particle size for potential solutions. Furthermore, the '112 patent does not provide any teaching or suggestion in this regard and as discussed above is cited by the Examiner for its disclosure of a bone cement composition that may contain drugs such as antibiotics. Therefore,

one of skill in the art would not have been motivated to modify or combine the reference teachings to arrive at the claimed invention.

Second, the cited prior art references, even when combined, do not teach or suggest all the claim limitations. As described above, a critical feature of the novel biomaterial compound of the present invention is its stabilization through the selection of specific chemical elements that can substitute for the chemical elements calcium, oxygen, or phosphorous in its calcium phosphate lattice. Such chemical elements are those with an ionic radius of approximately 0.1 to 0.6Å (see, e.g., exemplary chemical elements in Table 2 of the specification). Also as described above, the Examiner points to the '629 patent in an attempt to cite a reference disclosing the substitution of such chemical elements. However, the '629 patent clearly contemplates a composition comprising biocompatible particles dispersed in a matrix where the particles may be substituted by items such as cellulose ethers, collagen, or hyaluronic acid, and not the substitution in the present invention of *chemical elements* such as silicon or boron that are of a size sufficient to allow for them to fit into the crystal lattice structure of the claimed compound. When the '629 patent states that particles of any size may be utilized, it is stated that particles "even as small as about 100 to 700 microns" may be used (see column 4, lines 36 to 39 of the specification of the '629 patent). One of skill in the art would understand that the '629 patent is referring to particles that, while small, are not the same as *chemical elements* measured at the Angstrom level. None of the cited references disclose such elemental substitutions, and even when combined, would not teach or suggest this claim limitation to one of skill in the art.

In summary, because the cited prior art references, even when combined, do not teach or suggest all the claim limitations and because one of skill in the art would not be motivated to combine the cited references, a *prima facie* case of obviousness has not been established and the rejection under 35 U.S.C. §103(a) should be withdrawn.

Claims 1 and 53-57 also stand rejected under 35 U.S.C. §103(a) in view of the '729, '112, and '629 patents, further in view of Kasuga *et al.* ("the '878 patent"). This rejection is respectfully traversed.

The Examiner cites the '729, '112, and '629 patents for the same reasons described above. The Examiner cites the '878 patent for its disclosure of a process for producing biomaterials comprising compounds such as calcium phosphate, calcium oxide, phosphorus pentoxide, silicon dioxide, magnesium oxide, and aluminum oxide and that can optionally contain boron oxide. The biomaterials described in the '878 patent are also described as useful for producing artificial bones or dental implants. However, in spite of the disclosures described by the Examiner in the '729, '112, '628, and '878 patents, the Examiner has failed to establish a *prima facie* case of obviousness.

First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine the reference teachings to arrive at the claimed invention. The deficiencies of the '729, '112, and '629 patents in this regard, used alone or in combination, have been discussed above. The '878 patent fails to provide any additional suggestion or motivation to one of skill in the art to modify the references or combine the reference teachings to arrive at the claimed invention.

The '878 patent is structurally different compared to the presently claimed invention. The implant of the '878 patent is a physical dispersion of crystallized glass or calcium phosphate within a skeleton of zirconia, which provides for increased mechanical properties. The fact that the '878 patent is directed to a "glass" structurally identifies the material as being different from the presently claimed bioresorbable compound. Furthermore, it is only in the later steps of the '878 patent's process that the glass is heated to form a crystallized powder which is then mixed with zirconia or alumina that acts to "partially stabilize zirconia" by which it is meant that the zirconia is prepared to attain high strength and high toughness with respect to stress-induced transformation (column 6, lines 38-44). However, in the present invention, stabilization of the

compound is achieved by selecting chemical elements that can substitute for the chemical elements calcium, oxygen, or phosphorous in a calcium phosphate lattice. One of skill in the art attempting to develop the presently claimed compound would not turn to a reference such as the '878 patent that not only discloses a material that is structurally different from that in the present invention, but that discloses a stabilization method that is different from that employed in the present invention. Therefore, one of skill in the art would not have been motivated to modify or combine the reference teachings to arrive at the claimed invention.

Second, the cited prior art references, even when combined, do not teach or suggest all the claim limitations. The deficiencies of the '729, '112, and '629 patents in this regard, used alone or in combination, have been discussed above. As described above, a critical feature of the novel biomaterial compound of the present invention is its stabilization through the selection of specific chemical elements with an ionic radius of approximately 0.1 to 0.6Å that can substitute for the chemical elements calcium, oxygen, or phosphorous in its calcium phosphate lattice. The '878 patent does not disclose such elemental substitution, much less elemental substitution for a bioresorbable compound. Therefore, the '878 patent fails to provide any additional disclosure, individually or when combined with the other cited references, that would teach or suggest this aspect of the claims.

In summary, because the cited prior art references, even when combined, do not teach or suggest all the claim limitations and because one of skill in the art would not be motivated to combine the cited references, a *prima facie* case of obviousness has not been established and the rejection under 35 U.S.C. §103(a) should be withdrawn.

CONCLUSION

In view of the aforementioned remarks made above, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. §103(a) are overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or any additional fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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